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09/868,276
Attorney Docket No.: 015058-003210US

Assistant Commissioner for Patents
Washington, D.C. 20231

On December 18, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: Sygnal Arnold

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ALLEN *et al.*

Application No.: 09/868,276

Filed: June 15, 2001

For: PROTEASE INHIBITORS

Examiner: Not yet assigned

Art Unit: Not yet assigned

COMMUNICATION UNDER

37 C.F.R. §§ 1.821-1.825

Box SEQUENCE
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Communication is filed in response to the Notification to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, 37 C.F.R. §§ 1.821-1.825 that accompanied the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) mailed August 27, 2001.

REMARKS

The Notification to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures indicates that the present application fails to comply with requirements of 37 C.F.R. §§ 1.821-1.825. Applicants assert that the application as filed contains no sequences encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a), 37 CFR § 1.821(a)(1) or CFR § 1.821(a)(2).

A review of the entire application failed to demonstrate any sequence that is required under 37 CFR §§ 1.821-1.825 to be included in a Sequence Listing. The only occurrence of a sequence of amino acids occurs in the specification in the structural illustrations on page 3, lines 5 and 6, repeated on page 7, lines 1 and 2, page 12, lines preceding line 10, and in claims 1 and 2, with the pertinent definitions for the symbols occurring on page 5, lines 3-6, repeated on page 8, line 32, through page 9, lines 1-3, page 16, lines 5-8, and in claims 1 and 2, consisting of "Q, Q¹, Q², Q³, L¹, L², L³ and L⁴" stated to "independently at each occurrence represent N-natural or unnatural amino acid side chain" (emphasis added). The relevant portions of 37 CFR § 1.821(a) state, "amino acid sequences as used in §§ 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids...Sequences with fewer than four specifically defined...amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa"...defined in accordance with World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2, herin incorporated by reference. (Herinafter "WIPO Standard ST.25 (1998)")." (emphasis added).

Further, in the paragraph beginning on line 7, on page 164, the following statement occurs: "The term "unnatural amino acid", as used herein, is intended to represent the 'D' form of the twenty naturally occurring amino acids described above. It

is further understood that the term unnatural amino acid includes homologues of the natural aminoacids, and synthetically modified form of the natural amino acids." (emphasis added). From 37 CFR § 1.821(a)(2), the relevant portion states "Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in WIPO Standard ST.25 (1998), Appendix 2, Table 3. Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition." (emphasis added).

The above sections from the specification clearly specify that each of the sequences defined by "Q, Q¹, Q², Q³", or "L¹, L², L³ and L⁴" in the structural diagrams have a multitude of optional amino acid substitutions at each position, including amino acid D-forms, further modified by the presence of chemical substituents on each terminal residue in a ring structure. Since WIPO Standard ST.25 (1998), Appendix 2, Table 3 contains only the twenty commonly occurring L-form amino acids, plus Glx or Asx, the representations in any Sequence Listing for all amino acids occurring at these positions can only be accounted for by the use of "Xaa". Since the present application contains no other sequences, and there are no sequences where there are four "specifically defined" amino acids in the sequence other than "Xaa", no Sequence Listing is required.

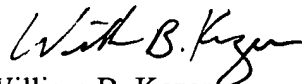
It is respectfully submitted that the assertion that the present application fails to comply with requirements of 37 C.F.R. §§ 1.821-1.825 and requires the submission of a Sequence Listing is in error. Therefore, Applicants respectfully request withdrawal of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

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PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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